

Medmarc Loss Control Podcast Transcript:

Social Media

- Erlisa King: Welcome to the Medmarc podcast network. My name is Erlisa King, Medmarc's Loss Control Advisor. Today, I will be speaking with attorneys Mark DuVal and Mark Gardner about how medical technology and life sciences companies can take advantage of social media channels in a manner that is beneficial to their bottom line, and compliant with FDA regulations. Mark DuVal is the President of DuVal and Associates, a Minneapolis area law firm that counsels medical technology and life sciences companies. His practice includes providing strategic regulatory advice, developing compliance programs, counseling and reimbursement issues, and interfacing on behalf of companies with the FDA on matters related to product approvals and clearances, clinical trials, policy issues, and appeals. Mark Gardner is an associate at DuVal and Associates. His practice focuses on compliance and promotions, specifically relating to appropriate and lawful off-label dissemination procedures, sales contracts, labeling and advertising review, continuing medical education programs, product launch campaigns, preapproval communication programs, direct-to-consumer advertising, and domestic and international Web strategy. Welcome, gentlemen.
- Mark DuVal: Thank you very much.
- Mark Gardner: Thank you.
- Erlisa King: Can you describe for us what exactly the term "social media" encompasses?
- Mark DuVal: Well, I'll take a first shot at it. This is Mark DuVal. I'm not a social media guru, although we all participate in social media in one extent or another, but we all certainly know the big names: Facebook, YouTube, Foursquare, Twitter, LinkedIn, and there's blogs of varying shapes, and sizes, and kinds. So, these are all – they all have in common, I guess, the Internet, and it's all ways in which people connect with themselves to talk about issues and things of importance to them. So, social media is a pretty broad – it encompasses a broad net, but what they have in common of course, is the Internet. Mark, do you have any thoughts on that?

You're a little younger than I am and a lot more active on social media than I am I must admit. So, what are your thoughts?

Mark Gardner:

I think you hit it on the head there. You're starting to see a kinda evolution towards this Web 2.0 is what some journalists describe it as, but basically the Internet is evolving into this more social state where people are interacting and companies are interacting. Obviously, the guests and the people that are listening in here as, their patients and their physicians that they serve are also interacting with social media. So, I think we're gonna continue to see an evolution here and social media is not going away any time soon.

Erlisa King:

Can one of you talk about why social media is important to the life sciences industry?

Mark Gardner:

Yeah, and this is Mark Gardner here. Just to kinda extend what I just stated, it's really a marketing channel. My background is a little unique. Before becoming an attorney, I was a product manager at a patent device industry ten years prior to becoming an attorney. I was always concentrating on different channels. The biggest channel any company usually utilizes is a sales rep. Now, this social media channel has come along and a lot of the companies obviously are interested in that because it's a big communication channel, is what it really is, to get the word out on products and provide more information to patients and physicians. So, social media is gonna continue to be used, and that's why it is important to life sciences industries.

Mark DuVal:

And you know, from my perspective, what I like about Mark being a little bit younger than I, he's got a fairly new perspective and a marketing perspective on these issues. I kinda have the older guy, been around there, done that, seen the evolution of the law, and the regulations, and the FDA's thinking for a long time as well. There's always been this inherent tension. I've been interviewed many times by the *Pharmaceutical Executive* and other publications. Three to five years ago, we were talking about this developing trend of social media, and what's gonna go on with blogging, and whatnot. Well, in every year, the developments just leapfrog one another. The inherent tension is people want to communicate freely about topics, which include drugs, medical devices, dietary supplements, you name it – biologics. In a highly regulated industry, you wanna control that environment in some

way, fashion, or form in order to be compliant. That's where the rubber meets the road is when the company, which is a highly regulated institution in this field wants to play with a highly unregulated and very free-flowing venue like social media. How the two shall meet remains to be seen. I know FDA is thinking a lot about this, just like when they thought about rules for the Internet way back when, which we can discuss a little later, but that's – it's obviously vitally important for companies to wanna stay current and to be participative, but it's also just as equally important that we be mindful of our regulatory obligations in this arena.

Erlisa King: Can you share with us how the FDA plays a part in this as far as regulating social media?

Mark DuVal: Well, in some respects, FDA's view probably has not changed. I mean they've had to encounter new venues. I mean, I remember when they first encountered the Internet, and they were asked – they asked people like me, "What do you think? How do you think we should regulate the Internet?" My basic position was, "The underlying and basic rules still apply." They apply to this medium as well as any other medium. We're gonna be challenged factually with how it differs, how they present themselves, and what can be done with the Internet. The same is true of social media. The same underlying rules really apply, but I think given this new administration in the FDA and the Presidency generally, they have a tendency to wanna regulate more rather than less. I think they will make an attempt to try and provide some direction, and some modification to the existing rules, and apply them to social media. That's okay as long as they don't forget that there are some underlying principles that underlie everything and that is: We gotta be truthful; we gotta be not misleading, and we gotta be fairly balanced, and provide adequate directions for use about our products. Then, we always have to keep those basic principles in mind when we're talking about the nuances, which are surely new for us, but the nuances that are presented by social media, but we'll get there.

Again, I think we all are welcoming some agency direction. I don't think they have to overdo it. I think that if they get too concrete about it, the rules of the game, of engagement of social media will change before their very eyes. So, they shouldn't invest too much time, I think, because things will be changing as we go. They need

to think about the more static principles rather than the dynamic medium. Mark, do you have any thoughts on that?

Mark Gardner: You know, I think that pretty well summarizes it. I think FDA ultimately will probably come out with some guidance because you have groups like Google and certainly all of the social media players that they do need guidance because it is somewhat different for example, when you're doing a Web search. You're not – you don't have the same amount of real estate as you do with say even a magazine ad when you're doing a search on Google. So, we'll just have to wait and see what they come out with – some guidance specific to social media, which they have hinted at doing.

Mark DuVal: Yeah, I think it's interesting to note, if you look at FDA's hearing that they had on this and Google gave some very thoughtful proposals. Was it of November of last year, I believe, Mark? Google and a number of other companies, but particularly Google gave some very thoughtful proposals born out of what Mark said. The – look. We are inherently limited in real estate with this medium. Is the FDA gonna try and change the medium or are they really gonna – are they gonna succumb to the fact, or just administratively recognize the fact the medium can't change for FDA. FDA needs to change for the medium. So, there will have to be some concessions and some give and take to go along, so that we don't tarnish the free-flow and exchange of medical and scientific information, but we still protect the patients and give the physicians proper information to act upon.

Erlisa King: Right, that's interesting. What are some of the legal and regulatory consequences for using social media and properly?

Mark Gardner: Well, certainly under the existing regs, FDA can and has in the past sent out warning letters to companies that they felt violated, for example, the direct-to-consumer guidance, direct-to-consumer advertising guidance that exists. Actually, last year, 14 warning letters went out to various companies asking them to cease their – ordering them rather, to cease and desist what the FDA deemed violative. So, there is FDA action. I just read an ad recently where another company – I won't say their name.

Mark DuVal: Novartis.

Mark Gardner: Novartis, but they were –

Mark DuVal: Go ahead. Talk about it.

Mark Gardner: They were just kinda told by FDA that they needed to stop using a Facebook widget that promoted a leukemia drug. So, this is very, very dynamic and we're seeing things happen daily. This particular article that I read was just August 6th, so a few days ago. There's other issues that emanate from this, where you may have some HIPPA issues if there's protected health information that is shown on a social media website, or what if there's an MDR that occurs if you're a device company and some report that you may receive over social media: Do you need to report that? Reimbursement or off-label issues, there's medical malpractice, potential issues related to product liability. So, it goes on and on. We certainly provide that insight to our clients when they decide to go live with social media because those are some of the things that the marketers may not be thinking of. They just wanna get to market with their message, but we certainly wanna keep our clients' best interest in mind and let them know that there are some hazards associated with this medium as well.

Mark DuVal: The bottom line for the marketers is that there's no question we could participate if we wanted to as an industry in social media. The issue I think is properly framed by your question. So then, what are the consequences? The consequences are that A.) You're gonna learn information and you may have a duty to act upon that information. You may have a duty to participate, and clarify, or explain certain comments that are being made. So, if you're gonna participate actively as a company on blog of some sort, you may learn things from a medical device or an adverse drug experience reporting standpoint that has to be reported to the government. You may find out things from a product liability standpoint about the design of your product. You may hear warnings about a product. You may have to modify things there. You may learn about privacy issues that you have to intercede on. You may have – hear about reimbursement advice being given about your product that is really not correct and you may at some point, have a duty to participate in that. You may hear about off-label information and have to direct people to recognize that this is not an approved use of your product. So, there's no question we could, as an industry, participate. It's a matter of, "Are we fully equipped and funded to participate in the manner in which we are – we should and are we –

do we wanna do that consistently?" When will the government imbue to us when there should be involvement on our part?

That's a difficult call as well. I don't think you have any obligation to participate, and if you do passively, do you have obligations? Certainly, you do if you do actively. These are all lines that have gotta be clarified and drawn. Everybody has to figure out. Some of it will be institutionalized and/or put out by the FDA in terms of governance for the entire industry. Some of it will be just individual decision making by individual companies, depending upon the level of cultural risk each company wants to take.

Erlisa King: Okay, wow. This is a very interesting topic. We look forward to your webinar on August the 25th. Gentlemen, thank you for your time today.

Mark DuVal: Thank you.

Mark Gardner: You're welcome.

Erlisa King: If you would like to learn more about this topic, I encourage you to visit medmarcprotect.com. That's M-E-D-M-A-R-C-protect.com. Here, you will be able to access the companion webinar and other supporting materials on this cutting edge topic. Thank you for joining us and be sure to check back for additional podcasts on product liability loss control topics from Medmarc.

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